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AUG 5 - 2005

510(k) Summary
for
UGYTEX® Dual Knit Mesh

1. SPONSOR

Sofradim Production
116 Avenue du formans
01600 Trevoux
France

Contact: Christophe Cosson
Telephone: 33 (0)4 74 08 90 00
Facsimile: 33 (0)4 74 08 90 02

2. DEVICE NAME

Proprietary Name: UGYTEX® Dual Knit Mesh
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh

3. PREDICATE DEVICES

Sofradim UGYTEX® Mesh K033376

4. DEVICE DESCRIPTION

The Sofradim UGYTEX® Dual Knit Mesh is a monofilament, polypropylene mesh coated in the central portion with an absorbable hydrophilic film of porcine collagen. The nonabsorbable, polypropylene mesh provides a long-term reinforcement for support structures. The hydrophilic film minimizes visceral attachment to the mesh which may occur during the healing process.

The UGYTEX Dual Knit Mesh will be offered in various configurations which may include a rectangular sheet, anterior repair system and posterior repair system.

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5. INDICATIONS FOR USE

The UGYTEX® Dual Knit Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The UGYTEX® Dual Knit Mesh is substantially equivalent in material, function, performance and design to the predicate UGYTEX® Mesh.

7. PERFORMANCE TESTING

The appropriate testing was performed to determine the performance characteristics of the mesh. The test results showed that the Sofradim UGYTEX® Dual Knit Mesh is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Sofradim Production
c/o Pamela Papineau, RAC
Consultant to Sofradim Production
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K051503
Trade/Device Name: UGYTEX® Dual Knit Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 6, 2005
Received: June 7, 2005

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051503

510(k) Number (if known):

Device Name: UGYTEX® Dual Knit Mesh

Indications For Use:

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Prescription Use __X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051503